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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,440	10/16/2001	Michael Greenstein	10004416	5699

7590 07/14/2006

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)
	09/981,440	GREENSTEIN ET AL.
	Examiner	Art Unit
	Ann Y. Lam	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,23 and 24* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2006 has been entered.

Status of Claims

Claims 19 and 20 have been canceled.

Claims 21-22 have been withdrawn.

Claims 1-18, 23 and 24 are currently pending.

Claim Objections

Claims 2-18, 23 and 24 are objected to because of the following informalities: --point-of-care—should be inserted before “miniature” in the preamble of each of these claims, to make it consistent with claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 1, 2, 10-18 and 24, are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Laugharn et al., 6,719,449.

Zou et al. disclose the invention substantially as claimed. More specifically, as to claims 1 and 2, Zou et al. disclose a point-of-care miniature analytical device with thermal regulation (see col. 2, lines 29-32, disclosing a miniaturized reaction chip with thermal control; see also column 4, line 65 – col. 5, line 1, disclosing typical dimensions of the device) comprising:

a cartridge (element 5, see fig. 4) comprising one or more portions constructed of a material, wherein the one or more portions define an array of temperature-controlled zones (chambers 6, see col. 2, line 67) including reactants (col. 4, line 13), and wherein each said temperature-controlled zone is constrained by cartridge portions that surround an area of space in which a reactant is contained and confine the reactant from flowing into other of said temperature-controlled zones (fig. 4, disclosing each chamber 6 to be isolated from other chambers),

and wherein the cartridge portions include clear or translucent portions (i.e., element 5, disclosed as being made of glass in column 3, lines 11-12) that allow direct irradiation of reactant molecules to facilitate thermal regulation of the reactants;

an array of heat source (13, see fig. 4) wherein the array of heat sources is positioned to correspond to the array of temperature-controlled zones so that each heat source is arranged to provide temperature regulation to a corresponding temperature-controlled zone, and wherein the heat sources emit localized radiation to provide heating in the corresponding temperature zone (col. 2, lines 63-67, disclosing an array of blocks for each chamber 6, and col. 3, lines 63-66, disclosing heater and sensor 13 on the top of each block 1);

a temperature monitor that monitors reactant temperature (sensor 13, col. 3, lines 54-64); and

a modulator that modulates the array of heat sources to regulate temperature in one or more of the corresponding temperature-controlled zones (col. 2, lines 42-43, disclosing individually controlled heaters and sensors);

whereby each temperature-controlled zone is controllable to a designated temperature (col. 1, lines 53-54, and col. 2, lines 42-43, disclosing independently and individually controlled heaters and sensors),

The Office notes that the limitation regarding the cartridge portions being clear or translucent portions (which is disclosed by Zou et al. as element 5, being made of glass in column 3, lines 11-12) are capable of allowing direct irradiation of reactant molecules to facilitate thermal regulation of the reactants, and thus the prior art reference Zou et al.

meets this claimed limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the element (5) disclosed by Zou et al. as being made of glass is capable of performing the intended use because a glass material is capable of allowing direct irradiation of reactant molecules to facilitate thermal regulation of the reactants.

However Zou et al. do not teach that the temperature monitor is an optical temperature monitor, not in contact with the cartridge and disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones, that monitors reactant temperature by measuring electromagnetic radiation. (Rather, Zou et al. teach that the temperature monitor is a resistive material (col. 3, line 54-56).

However, Laugharn et al. teach a device for exposing a biological sample to heat (col. 1, lines 45-58) and that heating of individual wells can be determined by an infrared thermal measuring device directed at the top of a vessel collimated so as to view only the well of interest and that this provides non-contact means of analysis that is not readily available in the conventional devices (col. 18, line 63 – col. 19, line 5). This infrared thermal measuring device is considered to be an optical temperature monitor not in contact with a cartridge and disposed adjacent to the cartridge surrounding the zones in the cartridge. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an infrared temperature-sensing device as taught by Laugharn et al. in place of the temperature sensing device in the Zou et al.

device because Laugharn et al. teach that an infrared temperature-sensing device provides the advantage of allowing non-contact analysis. One of ordinary skill in the art would have reasonable expectation of success in utilizing an infrared temperature-sensing device as taught by Laugharn et al. as the temperature sensor in the device taught by Zou et al. because Laugharn et al. teach that each individual well, or reaction chamber, such as the Zou et al. reaction chambers, can be monitored. Also, both references teach miniaturization of the devices (see Zou et al., col. 2, lines 29-32; and see Laugharn et al., col. 37, line 66 – col. 38, line 7), which support that one of ordinary skill in the art would have reasonable expectation of success in modifying the Zou et al. device in view of the teachings of Laugharn et al., in which it is taught that the structural elements are also miniaturized.

As to claims 2, 10-18 and 24, Zou et al. teach the limitations as follows.

As to claim 2, the array of heat sources comprises electromagnetic radiation emitters (col. 3, lines 54-56).

As to claim 10, the array of heat sources (13) are considered to be comprised of internal heat generators because the heat sources are internal to the device as shown in figure 4 and are adjoined to the reactants and generate internal heat within the reactants.

As to claim 11, the internal heat generators comprise resistive heaters (col. 5, lines 14-15), inductive heaters or Peltier heaters.

As to claim 12, an array of electrical leads (16, col. 3 line 66 – col. 4, line 1) correspond with the internal heat generators.

As to claim 13, the array of heat sources are considered external heaters because the heaters (13) are external to the chambers (6), (see fig. 4).

As to claim 14, a power supply drives current to increase the temperature of the zones (col. 2, lines 42-43, and col. 5, lines 14-15).

As to claim 15, a controller coupled to said power supply controls the drive current (col. 2, lines 42-43, and col. 5, lines 14-15 and 32-35).

As to claim 16, the controller is capable of modulating the power supply based on a temperature measured from the temperature-controlled zones (col. 2, lines 42-46, and col. 5, lines 14-15 and 32-35.)

As to claim 17, an array of temperature monitors is positioned to correspond to the array of temperature controlled zones (col. 3, line 64.)

As to claim 18, said reactants comprise assay elements for body fluid analysis (col. 1, lines 12-13, and lines 52-59.)

As to claim 24, the heat source (col. 3, lines 54-56) is capable of providing a temperature that is maintained at a desired temperature (col. 2, lines 42-46).

II. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Laugharn et al., 6,719,449, as applied to claim 1, and further in view of Austin et al., 6,203,683.

Zou et al. in view of Laugharn et al. disclose the invention substantially as claimed (see above regarding claim 1). While Zou et al. teach both heating and sensing temperature of a reaction chamber, Zou et al. however do not specifically disclose a

feedback loop including use of the reactant temperature to modulate a power supply that drives the array of heat sources.

However Laugharn et al. teach that the infrared temperature sensor may input temperature readings to a computer which will alter parameters regarding the treatment of materials according to the temperature of the sample (col. 19, lines 9-16). Moreover, the teachings of Austin et al. provide a specific motivation to provide a feedback loop in a device such as the Zou et al. device, as further explained below. Austin et al. teach a thermometer and a temperature modulator that changes the temperature of the heating source (col. 11, lines 10-16). Austin et al. also disclose means to improve temperature control (col. 11, lines 16-19). Thus, Austin et al. teach that temperature control is desirable and that this can be achieved through a thermometer and temperature modulator. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a feedback loop in the Zou et al. device because Austin et al. teach the desirability of modulating the temperature of the heating source for temperature control. One of ordinary skill in the art would recognize the benefits of temperature control in performing a reaction as it provides the ability to modulate temperature of reactants for convenience and accuracy of the reaction being performed. More specifically, Austin et al. teach the desirability of temperature control (col. 11, lines 16-19) and Austin et al. specifically teach that the chambers of the disclosed devices can be used for reactions involving DNA such as PCR, polymerase chain reaction (col. 2, lines 45-46, and col. 3, lines 19-13). Thus one of ordinary skill in the art would recognize the benefits of temperature control in the Zou et al. reaction, which is also

disclosed as a polymerase chain reaction (col. 5, lines 46-48). Also, one of ordinary skill in the art would have reasonable expectation of success in modifying the Zou et al. device to provide a feedback loop, such as that taught by Laugharn et al, because Laugharn et al. teach that a feedback loop can be provided in a device that utilizes a radiation heat source and an *optical* temperature monitor.

III. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Laugharn et al., 6,719,449, as applied to claim 2, and further in view of Austin et al., 6,203,683, and Miyazaki et al., 5,599,502.

Zou et al. in view of Laugharn et al. disclose the invention substantially as claimed (see above), except for the light source being an infrared laser. (Rather Zou et al. teach that the heat source is a resistive material—see column 3, lines 54-56).

However, Austin et al. teach that a wire (i.e., resistive heater) can be used to heat an array of chambers for holding reactants and that heating could also be achieved by infrared light sources shining on the chip (col. 8, lines 10-15). Thus, Austin et al. teach that resistive heaters and infrared light sources are functional equivalents in performing the function of heating an array of chambers for holding reactants. Moreover, both Zou et al. and Austin et al. teach that the chambers are for reactions involving DNA reagents (see Zou et al., col. 5, lines 46-48, and Austin et al., col. 2, lines 45-46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide infrared light sources to heat the chambers in the Zou et al. invention because Austin et al. teach that an infrared light source is a functional

equivalent to a resistive heater, such as the resistive heater in the Zou et al. invention, for heating reaction chambers for reactions such as those involve DNA reagents. The radiation emitted from the infrared light source is considered localized because it is emitted in a particular, i.e., localized, area.

However, while Austin et al. teach an infrared light source, Austin et al. do not specifically disclose that the infrared light source is a *laser*.

Miyazaki et al. however teach a device with chambers holding a liquid (col. 3, lines 3-18). Miyazaki et al. teach that the device can be used for reacting reagents (col. 7, lines 21-26). It is also taught by Miyazaki et al. that the liquid can be heated by the application of light form a light source such as infrared light source, e.g., infrared laser (col. 6, lines 23-28, and col. 9, lines 4-34.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a laser as the specific type of infrared light source that is generally taught by Austin et al. because Miyazaki et al. teach that a laser is a specific type of infrared light source that can be used for heating a liquid during a reaction. That is, while Austin et al. only teach an infrared light source in general but do not disclose a specific type of infrared light source, one of ordinary skill in the art would be motivated to use a laser because Miyazaki et al. teach that a laser is a specific type of infrared light source and that this type of infrared light source is also compatible for use with heating liquid during a reaction. Because Miyazaki et al. teach that an infrared laser can be used to heat liquid during a reaction, one of ordinary skill in the art would have reasonable expectation of success in utilizing an infrared laser to heat the reaction in the Zou et al. device.

As to claim 7, the infrared light laser is capable of generating infrared light of a different wavelength. (The Office notes that the claim does not recite from what the wavelength is different, and thus the claim will be interpreted broadly to mean that the wavelength is different from *any* other wavelength.)

Also, as to claims 8 and 9, none of the prior art references cited disclose that the light sources generate infrared light with a wavelength of at least .775 micrometers, or at most 7000 micrometers. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the prior art references (Zou et al., Laugharn et al. Austin et al. and Miyazaki et al.) disclose the general conditions of the claims, and infrared light with a wavelength as claimed is within a workable or optimum range and thus its discovery only involves routine skill in the art. For example, Zou et al. teach that the device is used for polymerase chain reactions (col. 1, lines 52-59 and col. 5, lines 45-47), as does Austin et al. (col. 9, lines 8-10). Utilizing an infrared wavelength as claimed by Applicant is within a workable or optimum range for heating reactants for purposes such as polymerase chain reactions.

IV. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Laugharn et al., 6,719,449, as applied to claim 2, and further in view of Austin et al., 6,203,683, and Miyazaki et al., 5,599,502, and Scott, 5,594,751.

Zou et al. in view of Laugharn et al. disclose the invention substantially as claimed (see above with respect to claims 1 and 2), except for the light source being a vertical cavity surface emitting laser, or a vertical cavity surface emitting laser that emits infrared light. However, the motivation to utilize a vertical cavity surface emitting laser is taught and suggested by Austin et al. in view of Miyazaki et al. and Scott, as described more fully below.

Although Zou et al. teach that the heat source is a resistive material (see column 3, lines 54-56), as opposed to an infrared light source, Austin et al. however teach that a resistive heater and an infrared light source are functional equivalents as heaters. Austin et al. teach that a wire (i.e., resistive heater) can be used to heat an array of chambers for holding reactants and that heating could also be achieved by infrared light sources shining on the chip (col. 8, lines 10-15). Thus, Austin et al. teach that resistive heaters and infrared light sources are functional equivalents in performing the function of heating an array of chambers for holding reactants. Moreover, both Zou et al. and Austin et al. teach that the chambers are for reactions involving DNA reagents (see Zou et al., col. 5, lines 46-48, and Austin et al., col. 2, lines 45-46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide infrared light sources to heat the chambers in the Zou et al. invention because Austin et al. teach that an infrared light source is a functional equivalent to a resistive heater, such as the resistive heater in the Zou et al. invention, for heating reaction chambers for reactions such as those involve DNA reagents. The radiation emitted from the infrared

light source is considered localized because it is emitted in a particular, i.e., localized, area.

However, while Austin et al. teach an infrared light source, Austin et al. do not specifically disclose that the infrared light source is a *laser.*

Miyazaki et al. however teach a device with chambers holding a liquid (col. 3, lines 3-18). Miyazaki et al. teach that the device can be used for reacting reagents (col. 7, lines 21-26). It is also taught by Miyazaki et al. that the liquid can be heated by the application of light from a light source such as infrared light source, e.g., infrared laser (col. 6, lines 23-28, and col. 9, lines 4-34.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a laser as the specific type of infrared light source that is generally taught by Austin et al. because Miyazaki et al. teach that a laser is a specific type of infrared light source that can be used for heating a liquid during a reaction. That is, while Austin et al. only teach an infrared light source in general but do not disclose a specific type of infrared light source, one of ordinary skill in the art would be motivated to use a laser because Miyazaki et al. teach that a laser is a specific type of infrared light source and that this type of infrared light source is also compatible for use with heating liquid during a reaction. Because Miyazaki et al. teach that an infrared laser can be used to heat liquid during a reaction, one of ordinary skill in the art would have reasonable expectation of success in utilizing an infrared laser to heat the reaction in the Zou et al. device. Moreover, Scott teaches that a vertical cavity surface emitting laser (vcsel) can emit infrared light, that is, a vcsel is a type of infrared laser (col. 8, lines 32-34). Scott

teaches a vertical cavity surface emitting laser that is highly-efficient (col. 1, lines 6-9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a vertical cavity surface emitting laser as disclosed by Scott as the specific type of infrared laser generally disclosed by Miyazaki because Scott teaches that a vertical cavity surface emitting laser is capable of emitting infrared wavelengths and has the advantage of being highly efficient.

Response to Arguments

Applicant's arguments filed June 22, 2006 have been considered but are not persuasive.

Applicant argues on page 8 of Applicant's response that the claimed invention is drawn to a "miniature analytical device" defined in the specification as "a device for conducting chemical and biological analytics tests ('assays') on a smaller scale as related to bench-top analytical equipment" (paragraph 5). Applicant maintains that the Zou et al. device is a larger device designed for use with bench- or base-related PCR elements such as external temperature balancing blocks, PCB (printed circuit board) thermal heating units, and "large heat sink[s]", citing Zou et al., column 2, lines 36-48. Applicant also asserts that Austin is also directed to a larger, PCR-type device that "includes data analysis equipment for the control of [] operations, and imaging equipment for the analysis of products, and that the bench-top apparatus of Laugharn et al. also includes processors, computer programs, feedback systems, and other elements associated with such larger scale equipment. Applicant also argues that claim

1 has been even further distinguished from the cited art by clarification that the claimed invention is drawn to "point-of-care" devices directed to smaller volumes than bench-top devices, pointing to paragraph 11 of the specification. Applicant states that the point-of-care miniature analytical device provide advantages that are not obvious in view of the cited bench-top art, citing paragraphs 5, 9, 11-12 and 14 of the specification.

Thus, Applicant argues, in short, that the claimed device is directed to a miniaturized device and more specifically a "point-of-care" device which is directed to smaller volumes than bench-top devices. These arguments are not persuasive because Zou et al. explicitly disclose a miniaturized reaction chip (see col. 2, lines 29-32). The Zou et al. invention is not disclosed as a bench-top apparatus, but is explicitly disclosed as a miniaturized reaction chip. The Office also notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art discloses the structural limitation of being a miniaturized analytical device. Zou et al. give an example of typical dimensions of the device, wherein the block (1) is 500 microns thick, the substrate (2) is 200 microns thick, the reaction chip (5) is 600 microns thick, (see col. 4, line 65 – col. 5, line 1). Thus, it is clear that the Zou et al. device is a miniaturized device and is smaller than a conventional bench-top device. Moreover, as to Applicant's argument that the Austin et al. device and the Laugharn et al. device are also directed to a bench-top apparatus and larger scale device, these arguments are also not persuasive. Austin et al. explicitly

disclose that the device is directed to handling of minute samples in a microfluidic channel (see abstract), and that microfluidic means physics and engineering principles that apply to fluids moving on a microscopic scale (col. 6, lines 57-58). Austin et al. give an example of the dimensions of the channels being 0.6 mm wide (col. 9, lines 54-55). Laugharn et al. also disclose miniature capillary-sized dimensions for fluid flow paths and microfluidic paths (col. 37, line 66 – col. 38, line 7). Thus, Austin et al. and Laugharn et al. also disclose miniature analytical devices, which further support that one of ordinary skill in the art would have reasonable expectation of success in modifying the miniaturized Zou et al. device according to the teachings of Austin et al. and Laugharn et al.

Applicant also argues on page 9 that Miyazaki et al. do not disclose elements such as an “optical temperature monitor” or “portions that allow direct...thermal regulation” of reactants in each zone. Applicant argues that these deficiencies are not cured by Laugharn et al., nor by the knowledge of one skilled in the art. This is not persuasive because the optical temperature monitor is disclosed by Laugharn et al. as indicated above, and the limitation regarding portions that allow direct...thermal regulation of reactants in each zone is disclosed by Zou et al. (col. 2, lines 42-43, disclosing individually controlled heaters and sensors).

Applicant also argues on pages 9 to 10 that the Office merely makes conclusory statements regarding the limitation of a feedback loop of claim 23. The motivation to provide a feedback loop has now been further elaborated in the above rejection

regarding claim 23 to more clearly set forth the reasons for modifying the Zou et al. device. In summary, the grounds for rejection is on the basis that

Laugharn et al. teach a feedback loop by teaching that the infrared temperature sensor may input temperature readings to a computer which will alter parameters regarding the treatment of materials according to the temperature of the sample (col. 19, lines 9-16). Moreover, Austin et al. teach a thermometer and a temperature modulator that changes the temperature of the heating source (col. 11, lines 10-16). Austin et al. also disclose means to improve temperature control (col. 11, lines 16-19). Thus, Austin et al. teach that temperature control is desirable and that this can be achieved through a thermometer and temperature modulator. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a feedback loop in the Zou et al. device because Austin et al. teach the desirability of modulating the temperature of the heating source for temperature control for reactions involving DNA such as PCR, polymerase chain reaction (col. 2, lines 45-46, and col. 3, lines 19-13). Thus one of ordinary skill in the art would recognize the benefits of temperature control in the Zou et al. reaction, which is also disclosed as a polymerase chain reaction (col. 5, lines 46-48). Also, one of ordinary skill in the art would have reasonable expectation of success in modifying the Zou et al. device to provide a feedback loop, such as that taught by Laugharn et al, because Laugharn et al. teach that a feedback loop can be provided in a device that utilizes a radiation heat source and an *optical* temperature monitor.

Applicant also argues on page 10 that the Office has not cited any evidence of specific reasons for motivation nor identified where such evidence might be found regarding, [it appears], the limitation of an optical temperature monitor. The motivation to provide an optical temperature monitor has now been further elaborated in the rejection of claim 1 above to more clearly set forth the reasons for providing an optical temperature monitor in the Zou et al. invention. In summary, Laugharn et al. teach an optical temperature monitor collimated so as to monitor only the well of interest and that this provides non-contact means of analysis that is not readily available in the conventional devices. One of ordinary skill in the art would be motivated to provide such an optical temperature monitor in the Zou et al. device because Laugharn et al. teach that it provides the advantage of allowing non-contact analysis.

Applicant also argues on page 11 that the Office fails to establish both the rationale for combining and the expectation of success for each of the cited references, and thus the case for obviousness is logically deficient. Applicant asserts that for example the Office provides no rationale (motivation or suggestion) at all as to why one would have combined the Laugharn et al. reference with the other references. In response the Office maintains that Laugharn et al. is combined with the Zou et al. reference for the teaching of the motivation to provide an optical temperature monitor for the advantage of allowing non-contact analysis as would be desirable in the Zou et al. device for DNA analysis (as previously described above). The Austin et al. reference is relied upon to teach the functional equivalence of infrared heaters and resistive heaters, which provide the motivation or suggestion to modify the Zou et al. device, as described

in the above rejection. Thus, the teachings of Laugharn et al. and Austin et al. are combined to the extent that they are relied upon to modify the Zou et al. device, as indicated in the above rejection.

Applicant also states on page 11 that similarly the Office provides no basis as to why one would expect to succeed in combining Miyazaki et al. with the other references to achieve the claimed invention. In response, the Office re-emphasizes that Austin et al. teach that an infrared light source is a functional equivalent to resistive heaters, such as the Zou et al. resistive heater, for heating reaction chambers. While Austin et al. do not specifically disclose that the infrared light source is a *laser,* one of ordinary skill in the art would be motivated to use an infrared laser as taught by Miyazaki et al. as the infrared light source generally disclosed by Austin et al. because Miyazaki et al. teach that a laser is a specific type of infrared light source and that this type of infrared light source is also compatible for use with heating liquid during a reaction. As described in the above rejection, because Miyazaki et al. teach that an infrared laser can be used to heat liquid during a reaction, one of ordinary skill in the art would have reasonable expectation of success in utilizing an infrared laser to heat the reaction in the Zou et al. device.

Applicant also states on page 11 that absent such necessary logical bases—e.g., why an ordinary artisan would modify PCR-type devices like those disclosed by Zou et al. and Austin et al. using features from unrelated sonic energy devices like that disclosed by Laugharn et al.—Applicant submits that these rejections cannot be maintained. In response, the Office notes that Laugharn et al. teach a device for

exposing a biological sample to heat (col. 1, lines 45-58) and that heating of individual wells can be determined by an infrared thermal measuring device directed at the top of a vessel collimated so as to view only the well of interest and that this provides non-contact means of analysis that is not readily available in the conventional devices (col. 18, line 63 – col. 19, line 5). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an infrared temperature-sensing device as taught by Laugharn et al. as the temperature sensing device in the Zou et al. device because Laugharn et al. teach that an infrared temperature-sensing device provides the advantage of allowing non-contact analysis, as would be desirable by one skilled in the art in performing a reaction. One of ordinary skill in the art would have reasonable expectation of success in utilizing an infrared temperature-sensing device as taught by Laugharn et al. as the temperature sensor in the device taught by Zou et al. because Laugharn et al. teach that each individual well, or reaction chamber, such as the Zou et al. reaction chambers, can be monitored. Also, both references teach miniaturization of the devices (see Zou et al., col. 2, lines 29-32; and see Laugharn et al., col. 37, line 66 – col. 38, line 7), which support that one of ordinary skill in the art would have reasonable expectation of success in modifying the Zou et al. device in view of the teachings of Laugharn et al., in which it is taught that the structural elements are also miniaturized.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Ann Y Lam 7/10/06
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